

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

This document relates to:

*The County of Cuyahoga v. Purdue
Pharma L.P., et al.*, Case No. 17-OP-45004

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P. et al.*,
Case No. 18-OP-45090

**MEMORANDUM IN SUPPORT OF DEFENDANTS'
MOTION TO EXCLUDE DAVID CUTLER'S
OPINIONS AND PROPOSED TESTIMONY**

TABLE OF CONTENTS

	<u>Page</u>
I. BACKGROUND	3
II. ARGUMENT.....	3
A. Cutler’s Opinions Do Not “Fit” the Case.	3
B. Cutler’s Aggregate Model is Impermissible and Irrelevant.....	7
C. Cutler’s Models Also Suffer from Numerous Serious Methodological Flaws.	8
1. Cutler Relies on Unreliable Inputs.....	8
2. Cutler’s Regression Models Do Not Reliably Estimate the Cause of Harms in Summit or Cuyahoga.	9
3. Cutler’s Estimate of Harms Attributable to All Opioids Is Based on Unreliable Data and Implicit Assumptions.	16
III. CONCLUSION	18

TABLE OF AUTHORITIES

	<u>Page(s)</u>
Cases	
<i>Ask Chemicals, LP v. Comput. Packages, Inc.</i> , 593 F. App'x 506 (6th Cir. 2014).....	9
<i>Bickerstaff v. Vassar Coll.</i> , 196 F.3d 435 (2d Cir. 1999).....	11
<i>Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.</i> , 582 F.3d 1227 (11th Cir. 2009).....	4
<i>Botnick v. Zimmer, Inc.</i> , 484 F. Supp. 2d 715 (N.D. Ohio 2007)	4
<i>Freeland v. AT&T Corp.</i> , 238 F.R.D. 130 (S.D.N.Y. 2006).....	11
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997)	9
<i>Grp. Health Plan, Inc. v. Philip Morris USA, Inc.</i> , 344 F.3d 753 (8th Cir. 2003).....	4
<i>In re REMEC Inc. Sec. Litig.</i> , 702 F. Supp. 2d 1202 (S.D. Cal. 2010)	11
<i>Morgan v. United Parcel Serv. of Am., Inc.</i> , 380 F.3d 459 (8th Cir. 2004).....	11
<i>New Haven v. Purdue Pharma, et al.</i> , No. CV-17-6086134-S (Conn. Supp. Jan. 8, 2019)	8
<i>Petre v. Norfolk S. Corp.</i> , 260 F. App'x 756 (6th Cir. 2007).....	8
<i>Petre v. Norfolk S. Ry. Co.</i> , 458 F. Supp. 2d 518 (N.D. Ohio 2006)	7
<i>Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.</i> , 711 F.3d 1348 (Fed. Cir. 2013).....	8
<i>Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.</i> , 49 F. Supp. 3d 385 (S.D.N.Y. 2014), <i>aff'd</i> , 638 F. App'x 43 (2d Cir. 2016)	11, 16

Roper v. Kawasaki Heavy Indus., Ltd.,
646 F. App’x 706 (11th Cir. 2016)..... 9

Defendants move to exclude Professor David Cutler from offering testimony regarding causation and damages. Plaintiffs retained Cutler to create the middle link in a multi-expert “estimate” of the harms caused by Defendants’ marketing and distribution of FDA-approved prescription opioid medications in the Track One Counties. To do so, Cutler multiples together a variety of aggregate, national-level estimates that are each premised on speculation and flawed assumptions, resulting in a layered opinion that relies on no economic expertise and amounts to little more than guesswork. Cutler’s opinions should be excluded for four independent reasons.

First, Cutler’s opinions are conceptually flawed, irrelevant, and unhelpful to the trier of fact because he fails to link any Defendant’s alleged misconduct to any harms in the Track One Counties. Indeed, Cutler ignores the real-world causal chain that Plaintiffs actually need to prove for liability—from each Defendant’s purported misconduct, to medically improper prescriptions and diversion, to addiction, to harms (e.g., deaths), to actual dollars spent by the Counties. Instead, Cutler does one of two things: (1) analyzes the correlation between the total quantity of prescription opioids shipped (by all distributors, not just Defendants) across a 400 county sample (not just the Track One Counties) and changes in mortality from all opioids (including illegal ones that Defendants had nothing to do with, like heroin and fentanyl); or (2) assumes that increases in opioid deaths are Defendants’ fault if he cannot explain the increases using economic and demographic indicators from within the same national 400-county sample. This aggregate, national estimate of the percentage of opioid-related mortality caused by an “average” shipment is not limited to Defendants’ or any individual Defendant’s shipments. Further, it is not limited to shipments that are alleged to be unlawful. As such, Cutler’s analysis does not provide proof that Defendants’ collective or individual marketing or distribution (be it lawful or allegedly unlawful) of prescription opioid medications contributed to any harms in the Track One Counties. Indeed,

Cutler does not analyze whether any Defendant's shipment actually had the "average" impact" on mortality (or any other harms) in Cuyahoga or Summit, or indeed, whether *any* such shipments were in fact caused by alleged misconduct. Thus, even ignoring the other fundamental flaws in his analyses, Cutler cannot opine that Defendants' individual or collective alleged misconduct caused any harm in the Track One Counties.

Second, the lynchpin by which Cutler seeks to tie his flawed "average shipment" estimate to alleged misconduct is either non-existent or incapable of linking alleged misconduct to any harms. With respect to distributors and pharmacies, Cutler claims that he can multiply his average impact estimate by percentages of purportedly wrongful prescription opioid shipments supplied to him by Plaintiffs' counsel. Those percentages are not supported by any facts or expert testimony in the record. They are nothing more than assumptions made by the lawyers who hired Cutler.

With respect to manufacturers, Cutler claims he can multiply his "average shipment" estimates by estimates of the percentage of prescriptions (not shipments) caused by "detailing" by manufacturer sales representatives (not false statements), which was supplied by another one of Plaintiffs' experts (Rosenthal). But Rosenthal's percentages do not even purport to show that misconduct by any Defendant led to improper or excess prescriptions, nor does she opine that any Defendant's prescriptions had the "average" impact on harms that Cutler calculates. There is thus no input Cutler can insert into his model to link the harms he analyzes to any alleged misconduct. Indisputably, Cutler's opinions do not "fit" Plaintiffs' theories, and are unreliable because they are not based on sufficient facts or data in the record. Therefore, they are not admissible.

Third, Cutler's opinions impermissibly aggregate the conduct of all manufacturers, distributors, and pharmacies, (*including non-defendants*). To the extent he measures the effect of prescription opioid shipments at all, he considers only the *total correlation* of all prescription

opioid shipments *with mortality across 400 counties* and makes no attempt to isolate whether any particular Defendant's conduct caused any "harms" in the Track One Counties.

Fourth, Cutler's models contain incurable methodological failures that render his opinions unreliable.

I. BACKGROUND

Plaintiffs rely on Cutler to estimate by regression analyses the percentage of opioid-related harms in the Track One Counties caused by Defendants' alleged misconduct. (Ex. 1, Cutler Report at ¶ 8.) But Cutler never actually answers this question. Instead, his "direct approach" purports to estimate the average causal effect of shipments on opioid mortality in 400 large counties across the country, and his "indirect approach" purports to measure opioid mortality that would have occurred based on certain demographic and economic factors, assigning blame for all residual mortality to Defendants. (*Id.* at ¶ 26.) Then, to estimate the percentage of harms attributable to Defendants' alleged misconduct, Cutler multiplies together three separate broad estimates, only one of which even partially relates to Cuyahoga or Summit:

Estimate #1: Cutler's estimate of prescription and illegal opioid mortality correlated with all prescription opioid shipments;

Estimate #2: Cutler's estimate of harms (e.g., crimes, juvenile removals, autopsies) attributable to prescription and illegal opioids; and

Estimate #3 for manufacturers: Rosenthal's estimate of prescriptions correlated with all detailing;

Estimate #3 for distributors and pharmacies: Plaintiffs' counsel's estimate of improper shipments.

II. ARGUMENT

A. Cutler's Opinions Do Not "Fit" Plaintiffs' Theory of the Case.

Courts routinely exclude causation experts who, like Cutler, offer opinions that fail to connect the alleged misconduct to the alleged injury. For example, in *Botnick v. Zimmer, Inc.*, this

Court held that, to be admitted under *Daubert*, the plaintiff's causation expert's testimony "must exhibit relevancy, *connecting his theory* of an alleged defect in the medical device to [the plaintiff's] injury." 484 F. Supp. 2d 715, 721 (N.D. Ohio 2007) (emphasis added). In excluding the expert, the Court determined that the testimony lacked that critical connection, as it was "not driven, as it must be, by the context of the issues in this case." *Id.* Other federal courts have reached similar conclusions. See *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1234-35 (11th Cir. 2009) ("because [the expert's] injury and damages opinion was not confined to charges that its liability theory would consider unlawful, it was too broad" and "ill fitting"); *Grp. Health Plan, Inc. v. Philip Morris USA, Inc.*, 344 F.3d 753, 761 (8th Cir. 2003) ("[T]he disconnect between [the expert's] work and the HMOs' theory of liability weighs heavily against the admission of his testimony under *Daubert* because it undermines the existence of a 'legal nexus between the injury and the defendants' wrongful conduct' and thus does not properly 'fit' the HMOs' case.") (citation omitted).

Like the expert in *Botnick*, Cutler should be excluded because his opinions are not tied to Plaintiffs' burden of proof. Despite specific allegations of unlawful marketing and distribution conduct, (Third Amended Complaint, County of Summit, et al. v. Purdue Pharma L.P., et al., ECF 1466 at ¶¶ 10, 101), Cutler does not attempt to link to any such conduct to any specific harms in the Track One Counties. For example, Cutler:

- **Does not isolate** what percentage of opioid prescriptions or shipments in the Track One Counties are linked to any alleged unlawful conduct by Defendants.
- **Does not attempt** to attribute any "harms" in the Track 1 Counties to any particular Defendant, any particular alleged misstatement(s), any "particular prescription," any "particular shipment" or group of particular shipments, or even any particular opioid or (legal or illegal) group of opioids. (Ex. 2, Cutler Dep. at 59:20–60:17.)
- "[C]an't say whether any of the increase in mortality [*i.e.*, the harms] that [he] attribute[s] to defendants resulted from individuals who actually got a prescription for one of the opioids that was manufactured or distributed by any defendant." (*Id.* at

358:21–359:13) (emphasis added).

- **Makes no effort** to disentangle the effect of Defendants’ conduct from that of non-defendants.
- **Does not even try** to separate the impact from illicit drugs like illegal fentanyl—instead opting to include all opioid-related harms, including from illegal drugs, in his models.

In fact, most of the harms Cutler attributes to Defendants are actually derived using unscientific “indirect” models. In these models he assumes that any increase in legal and illegal opioid deaths that he cannot explain using a far-from-comprehensive¹ collection of economic and demographic statistics must have been caused by Defendants. (Ex. 1, Cutler Report ¶ 76.) In short, he assumes his way to an opinion of causation. But an expert cannot “*assume*[] as truth the very issue that [Plaintiff] needs to *prove* in order to recover.” *Clark v. Takata Corp.*, 192 F.3d 750, 757 (7th Cir. 1999). Aside from being unhelpful, this method is a clear misapplication of the statistical tool he employs. (*See, e.g.*, Ex. 3, Murphy Report ¶¶ 151–56.)

To the extent he investigates the impact of shipments at all, Cutler simply analyzes the relationship at two points in time between (i) *all* prescription opioid shipments from both Defendants and *non-defendants*—whether alleged to have been caused by misconduct or not—in 400 counties across the country and (ii) opioid mortality (both prescription *and illegal*) in those counties. To do so, he conducts a regression that purports to “estimate” the “average impact” that each MME shipped had on mortality in these 400 different counties.² By relying on the “average impact” of all shipments on mortality in 400 different counties, Cutler purports to opine on causation *without* attempting to link any actual incidents of harm in Cuyahoga or Summit to any Defendant’s alleged misconduct in those counties.

¹ *See infra* section II.C.2.

² (Cutler Dep. at 63:6–19 (“we’re estimating the impact of the *average shipments* on harms. That doesn’t have to mean that each individual drug has the same impact; it rather means that what we’re getting is on net the relationship between them, that is the *average relationship*.”) (emphases added).)

Moreover, Cutler does not analyze whether his estimate of the “average impact” on mortality of all shipments in 400 different counties is representative of the alleged harms caused by any Defendant’s misconduct in Cuyahoga and Summit. Nor could he, as he does not analyze the impact of alleged wrongdoing on mortality (or any other “harm”); he looks only at the impact of all shipments. Compounding this flaw, he also fails to analyze whether any particular Defendant’s shipments—or even the collective of “Defendants’ shipments”—are consistent with the “average impact” he calculates.

Cutler’s assumption that each Defendant’s shipments had the “average impact” on mortality is unreasonable and unreliable given the vast array of medicines he includes in his analysis. For example, Cutler fails to distinguish:

- the effect of different types of prescription opioids sold or distributed by particular Defendants (immediate-release vs. extended-release; hydrocodone vs. oxycodone vs. fentanyl);
- the reason why an opioid was prescribed (acute pain vs. chronic pain vs. cancer pain);
- the length of the prescription; or
- the possibility that particular types of opioids may be more prone to diversion or more likely to contribute to the harms Cutler purportedly analyzed.

The failure to do so renders his conclusions unhelpful, unreliable, and inadmissible.

Recognizing this deficiency, Cutler claims that the effects of misconduct can be later separated from lawful conduct, with respect to manufacturers, by importing Rosenthal’s estimates of prescriptions purportedly caused by detailing. (Ex. 2, Cutler Dep. at 67:14–68:1). But he ignores Rosenthal’s concession that her model did **not** analyze the extent to which **any** alleged misconduct resulted in **any** improper prescriptions or harms—certainly not the “average” impact

on mortality that Cutler applies in his model.³ As discussed in more detail in the related Rosenthal *Daubert* motion, Rosenthal attempts to analyze only the extent to which *all detailing* by Manufacturers collectively resulted in opioid prescriptions, *not* harms. Thus, there is no input that Plaintiffs or Cutler can apply to Cutler’s “average impact” of all shipments calculation to make it “fit” the alleged harms in Cuyahoga and Summit for which Plaintiffs seek to recover.

Likewise, with respect to distributors and pharmacies Cutler claims that misconduct can be later separated from lawful conduct by importing percentages of shipments that Plaintiffs’ counsel told him should have been reported or blocked as described in paragraph 123 and Appendix III.J in Cutler’s report. Cutler testified that “[t]hese percentages were given to me by counsel who said that they were the output of Mr. McCann’s analysis,” but the truth is that the percentages appear nowhere in McCann’s report. (Ex. 2, Cutler Dep. at 594:11–595:3). Where did the percentages really come from? Nobody knows except Plaintiffs’ counsel. One thing is clear, though: Cutler’s opinions are not based on facts or data and should therefore be excluded.

B. Cutler’s Aggregate Model is Impermissible and Irrelevant.

Cutler’s opinions should be excluded for the independent reason that he offers opinions about only the alleged aggregate impact of all shipments of prescription opioids by Defendants and non-defendants alike on mortality across the nation. He does not even purport to assess the impact of any actual shipment by any particular Defendant (or all shipments by any Defendant, or even all shipments by all Defendants) on mortality in the Track One Counties. *See Petre v. Norfolk S. Ry. Co.*, 458 F. Supp. 2d 518, 543 (N.D. Ohio 2006) (a plaintiff cannot prove proximate cause where “the cause of injury may be reasonably attributed to things for which the defendant is not

³ In any event, Cutler has an order of operations problem. He first calculates the average impact of all shipments and only then multiplies by Rosenthal’s estimate. So even setting aside his misunderstanding of Rosenthal’s estimates, he assumes that each Defendant’s shipments had the same average effect, without any differentiation by product, time period, content, or Defendant.

responsible as to things for which he is responsible.”) (brackets and internal quotation marks omitted), *aff’d*, 260 F. App’x 756 (6th Cir. 2007). For example, he admits:

- “The analysis presented here does not attempt to uniquely apportion harm resulting from actions by any individual type of defendant.” (Ex. 1, Cutler Report at ¶ 31.)
- “[My model] is attributing the harm to the defendants as a whole. It is not attributing it to any specific defendant. And there is nothing in this report that says in order to attribute it to a specific defendant, follow the following procedure.” (Ex. 2, Cutler Dep. at 68:14–69:3.)

Thus, his opinions also should be excluded because he does not—and cannot—offer any opinions about whether any Defendant caused any of the harms he attributes to Defendants as a whole, much less how the cost of such harms should be allocated among Defendants.

C. Cutler’s Models Also Suffer from Numerous Serious Methodological Flaws.

In addition to the fatal issues discussed above, Cutler’s opinions should be excluded because they are the product of three separate estimates, each of which is based on a chain of speculation, unreliable data, and/or unsupported implicit assumptions. When multiplied together, the speculation also multiplies, rendering Cutler’s estimate of the percentage of harms attributable to Defendants’ alleged collective misconduct nothing more than guesswork. *See Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1374 (Fed. Cir. 2013) (“layered assumptions lack the hallmarks of genuinely useful expert testimony”). Indeed, Cutler engages in the exact type of exercise that one court described as “determining causation by conjecture” and “junk justice.” *New Haven v. Purdue Pharma, et al.*, No. CV-17-6086134-S, at 1 (Conn. Supp. Jan. 8, 2019) (dismissing identical opioid claims by counties in Connecticut).

1. Cutler Relies on Unreliable Inputs.

Cutler’s opinions about manufacturers are further unreliable because he multiplies his estimate of harms attributable to opioid shipments by Rosenthal’s flawed estimate of prescriptions caused by detailing to estimate “harms” attributable to “Defendants’ misconduct.” (*See* Rosenthal

Daubert). Because Rosenthal’s opinions are flawed and unreliable, and in fact do not address Manufacturers’ “misconduct” in any way, Cutler’s reliance on her opinion and resulting interrelated opinions are flawed and unreliable, too. *See Roper v. Kawasaki Heavy Indus., Ltd.*, 646 F. App’x 706, 708 (11th Cir. 2016) (affirming exclusion of expert for relying on another expert’s testimony, which itself was deemed unreliable).

Cutler’s opinions about distributors and pharmacies are similarly unreliable because he multiplies his estimate of all harms attributable to opioid shipments by inputs provided by Plaintiffs’ counsel that are not supported by any facts or expert testimony in the record. Therefore, Professor Cutler’s opinions are not based on sufficient facts or data, or even reliable assumptions. *See Ask Chemicals, LP v. Comput. Packages, Inc.*, 593 F. App’x 506, 510 (6th Cir. 2014) (affirming exclusion because expert’s “wholesale adoption of Plaintiff’s estimates, without revealing or apparently even evaluating the bases for those estimates, goes beyond relying on facts or data and instead cloaks unexamined assumptions in the authority of expert analysis”); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 138 (1997) (“nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert”).

2. *Cutler’s Regression Models Do Not Reliably Estimate the Cause of Harms in Summit or Cuyahoga.*

Another critically flawed input underpinning Cutler’s opinion is his estimate of the percentage of harms in Cuyahoga and Summit that are attributable to shipments of prescription opioid medications (including shipments by Defendants and non-defendants alike). There are four fatal flaws with the regression analyses Cutler employed to support this estimate.

First, Cutler himself admitted that it would be inappropriate to use his national model to estimate the relationship between mortality and shipments in any single county: “as an

econometrician you wouldn't use the analysis of this to predict for a single county, but rather one wants to use this to develop an estimate for the set of counties as a whole because that's what this -- this is what is describing the vast -- the average county in the data set, and that's what that regression coefficient is giving, and, therefore, it's appropriate to evaluate it at the average in the data set." (Ex. 2, Cutler Dep. at 533:20–534:5.) Indeed, Cutler testified that he would "need a different type of model entirely in order to estimate a coefficient for a single county." (*Id.* at 529:11–13.)

Despite this, Cutler relied on the results of his national regression models to estimate the percent of harms caused by Defendants' alleged misconduct in two specific counties—Cuyahoga and Summit. What is more, Cutler does not allow for any measure of error to account for the differences between the Track 1 Counties and the average counties he analyzed in his model. The underlying data suggest any such error rate is quite high. For example, under Cutler's theory, a county should have higher mortality if it receives more shipments. Yet, although Summit County received substantially higher prescription shipments than Cuyahoga County from 1997 to 2017, opioid-related mortality in Summit was at or below Cuyahoga's mortality until 2014. The lower mortality rate in Summit indicates that it takes more than simply counting shipments to understand causality. It also makes plain that Cutler's conclusions from his national model ***do not hold true in the Track 1 Counties***. Relatedly, as certain Defendants' expert Professor Murphy has shown, many counties in the lowest quartile for shipments are above the national average in terms of mortality, and many counties in the highest quartile for shipments are below the national average in terms of mortality. (Ex. 3, Murphy Report at ¶ 115). Cutler makes no effort to analyze any correlation let alone causal effect of shipments on mortality specifically in the Track One Counties.

Second, Cutler's direct regression models fail even in their narrow and irrelevant

purpose—to estimate the correlation between all shipments and all opioid mortality in 400 large counties—because they suffer from omitted-variable bias, and his indirect regression models do not even include a variable to measure the effect of shipments. The purpose of a regression model is to isolate the effect of an explanatory variable (here, shipments of prescription opioid medications) on a dependent variable (opioid mortality). A multiple regression analysis, like Cutler’s, “cannot prove causation. The most it can show is a correlation” *Morgan v. United Parcel Serv. of Am., Inc.*, 380 F.3d 459, 466 (8th Cir. 2004) (affirming summary judgment because flawed regressions could not satisfy burden of proof). To support admissible expert testimony, a regression must control for the major variables that impact the dependent variable. A regression analysis is inadmissible when it “omit[s] the major variables” because it falsely attributes the impacts of the missing variables to the explanatory variable. *Bickerstaff v. Vassar Coll.*, 196 F.3d 435, 449 (2d Cir. 1999); *Reed Const. Data Inc. v. McGraw-Hill Companies, Inc.*, 49 F. Supp. 3d 385, 396 (S.D.N.Y. 2014) (excluding analysis due to omitted-variable bias), *aff’d*, 638 F. App’x 43 (2d Cir. 2016); *In re REMEC Inc. Sec. Litig.*, 702 F. Supp. 2d 1202, 1273 (S.D. Cal. 2010) (same); *Freeland v. AT&T Corp.*, 238 F.R.D. 130, 149 (S.D.N.Y. 2006) (regression that omitted “two significant variables” was “essentially worthless” and “inadmissible”).

But that is precisely what Cutler’s direct shipment-mortality regression models do: they omit critical variables that impact mortality. For example, Cutler failed to include a control variable for the introduction of illicit fentanyl into illegal drug markets. (Ex. 2, Cutler Dep. at 432:3–21). Yet, he admits that there “was a rapid growth in misuse of illicit opioids and increase in mortality due to heroin and fentanyl which began around 2010.” (Ex. 1, Cutler Report ¶ 54). Thus, Cutler’s direct models inappropriately attribute increases in opioid mortality caused by these illicit drugs to Defendants.

Cutler justifies his attribution to Defendants of mortality (and other harms) caused by illegal opioids based on the unsupported theory that Defendants are responsible for all illegal opioid overdose deaths caused by a made up “thickening” of the illegal drug market. Specifically, Cutler developed an “indirect regression” to estimate the alleged impact of legal prescription opioid shipments on illegal opioid overdose deaths from 2011 to 2016. He explained that “[t]he share of deaths due to illicit opioids from 2011 to 2016 that is attributable to defendants’ misconduct is calculated using an indirect regression model that estimates the increase in illicit opioid mortality that is unexplained by social and demographic factors relative to the pre-2011 baseline.” (Ex. 1, Cutler Report at ¶ 102(3).) Cutler attributes to Defendants all harms that cannot be explained by his selected “social and demographic factors relative to the pre-2011 baseline.” Critically, however, because Cutler failed to include any variables in his regression to account for changes in the illegal drug markets that impacted illegal drug overdoses (such as declining heroin prices and the introduction of illicit fentanyl from China and other forms of illegal synthetic opioids), Cutler’s indirect model attributes deaths caused by those illegal drugs to Defendants. Cutler acknowledges that his failure to control for these and other omitted variables “has the potential to overstate the impact of defendants’ actions.” (Ex. 1, Cutler Report at ¶ 78, n.53.)

Recognizing these flaws, Cutler seeks to justify attributing to Defendants all increases in illegal opioid deaths caused by changing conditions in the illegal drug markets based on his theory that Defendants are responsible for “thickening” those markets:

The reason [markets for heroin] got to be so thick . . . is because there were so many people that had been addicted to opioids, and then when the opioid supply was reduced they went to look for other alternatives, and heroin was a cheaper other alternative. So that led more people into the market.

(Ex. 2, Cutler Dep. at 321:22–322:14.) Cutler claims “[t]hose markets are thicker because of the demand that was created by the misconduct on the part of the defendants.” (*Id.* at 438:10–16.)

But this reflects yet another fundamental flaw. Cutler has not done any analysis to support, quantify, or test his opinions about Defendants’ alleged “thickening” of illegal drug markets, and there is no support in the academic literature for this novel theory, either:

Q. You cannot quantify the contribution that pre-2010 shipments made to the presence or sophistication of drug networks in Cuyahoga or Summit after 2010?

A. Unfortunately we don’t have data on presence or the sophistication of drug networks anywhere. Because it’s an illegal good, we just don’t have that. So there’s really no economic way to try and do a quantification of that.

(Ex. 2, Cutler Dep. at 412:4–12.) So, he just made it up. Some data is available, however, and it contradicts Cutler’s theory of thickening markets. (See Ex. 3, Murphy Report at ¶ 161–165.) Moreover, his attempt to blame Defendants for *all* harms from the alleged thickening of illegal drug markets is inconsistent with his own report, where he opines that “the presence and sophistication of drug networks is [only] **partially** a result of opioid shipments prior to 2010, as they created ‘thicker markets’ for illegal products.” (Ex. 1, Cutler Report at ¶ 71) (emphasis added.) Because Cutler’s “thickening” opinion is not based on any quantifiable analysis, is inconsistent with his own report, and lacks acceptance in the economic field, it should be excluded.

Separately, Cutler also failed to include control variables in both his direct and indirect models reflecting the “deaths of despair” that have been widely studied in economic literature and by Cutler himself. These deaths are a result of the “cumulative disadvantage” resulting from “economic and social breakdown” that has plagued certain segments of the population.⁴ At his deposition, Cutler admitted (as he had in earlier papers commenting on Case and Deaton) that “the

⁴ See Ex. 4, Case, Anne, and Angus Deaton, “Mortality and Morbidity in the 21st Century,” Brookings Papers on Economic Activity, Spring 2017 (“Case and Deaton (2017)”), pp. 429, 445. “These slow-acting social forces . . . work through their effects on family, on spiritual fulfillment, and on how people perceive meaning and satisfaction in their lives in a way that goes beyond material success. At the same time, increasing distress, and the failure of life to turn out as expected, are consistent with people compensating through other risky behaviors such as abuse of alcohol and drug use[.]” *Id.* at 433-434.

theory that economic and social breakdown leads people to despair and that they then act in ways that may be harmful, for example, through heavy drinking, smoking, drug abuse, not taking preventive medications, and so on, that that is certainly correct at least in part.” (Ex. 2, Cutler Dep. at 480:13–20). Yet despite admitting that these factors are “very deep-seated indeed” and drive increases in mortality,⁵ Cutler conceded that his regression models cannot account for these “deep-seated” factors and the impact they have on mortality:

Q. Just like Case and Deaton, you also don’t have data to say whether their theory that these deaths -- increase in deaths in the ‘90s and 2000s are related to deep-seated social and demographic circumstances?

A. I wish I had the ability as a scholar and a human being to test that. They were unable to test it fully in their work. They showed some correlations. They were unable to test it fully in their work. I wasn’t able to -- I did not have access to any data they did not have access to.

(Ex. 2, Cutler Dep. at 485:24–486:11.)

Cutler testified that he “is explicitly hoping” other variables in his model account for these despair conditions, but he admitted that he “cannot give an econometric answer to the question of what impact including such variables [reflecting “deep-seated” deaths of despair] would have.” (*Id.* at 488:4, 558:22–559:14.) “Hoping,” however, does not satisfy the standard for expert testimony under Rule 702. Nor was Cutler limited to relying on hope, as opposed to economic analysis. Several of Defendants’ experts conducted analyses that accounted for these “deaths of despair” variables within the regression frameworks Cutler used and determined that doing so dramatically reduced or even eliminated Cutler’s “average” impact percentages.⁶ Cutler’s failure to include available variables reflecting the underlying conditions of deep-seated, long-term despair renders the causal conclusions from his regressions unreliable and inadmissible.

⁵ Case and Deaton (2017), p. 445.

⁶ See, e.g., Ex. 5 Cockburn Report at ¶¶ 101-105; Ex. 3, Murphy Report at ¶¶ 132-136 (“even simple proxies for despair that were available to Professor Cutler can have a large effect on his results”).

Third, Cutler inappropriately and unreliably uses mortality as a proxy for all of the non-mortality harms he attributes to Defendants—including addiction and mental health activity, children’s and family services, and juvenile court activity—without any attempt to determine whether the relationship between shipments of opioid medications and these disparate harms is the same. Specifically, the direct and indirect regression models Cutler employs to estimate his “average impact” percentages are based on the relationship between shipments of lawful prescription opioid medications and opioid-related mortality. After estimating the relationship between these two variables, Cutler then applies the “average impact” implied by his regressions to estimate the percentage of disparate non-mortality harms that were caused by shipments. For example, Cutler assumes that, if all prescription opioid shipments are correlated with an estimated X percent increase in opioid-related mortality across the country, then X percent of allegedly opioid-related child removals and juvenile court cases in Cuyahoga and Summit were due to those shipments. Yet Cutler admits he has done no analysis to support the use of national mortality as a proxy for the many distinct types of non-mortality harms in Cuyahoga and Summit:

- “Q. Well, let me -- it’s a true statement, right, that there’s a different relationship between foster care and opioid shipments than there is between opioid mortality and opioid shipments? A. I don’t know empirically whether the relationship would be similar or different. So I think you’re saying would there be a different empirical relationship. Because I can’t measure the empirical relationship the same way, I can’t do a comparison across those and say if they’re different.” (Ex. 2, Cutler Dep. at 453:16–454:4.)
- “I don’t have hard and fast empirical data to say with absolute certainty the effect if I could estimate it a different way would be stronger.” (*Id.* at 456:24–457:12.)

By using one constant measure of impact based only on his shipment-mortality regressions, Cutler fails to account for the obvious differences in harms across the allegedly damaged divisions. For example, an increase in mortality likely affects the medical examiner’s office, which autopsies victims of mortality, differently than it affects juvenile court cases. And to the extent the non-

mortality harms Cutler identifies are driven by opioid use disorder (“OUD”), the dramatic difference between relatively stable OUD rates and increasing opioid-related mortality rates suggests that the impact of shipments may be different for mortality than for other harms driven by addiction. Specifically, from 2002 to 2010, the OUD rate grew by only 14 percent while the opioid-related mortality rate grew by 67 percent. The divergence then became even sharper from 2015 to 2017—with the OUD rate falling by 13 percent and the opioid-related mortality rate rising by 34 percent. Even with these differential growth rates, however, Cutler assumes that his single estimate of the incremental impact of prescription opioid shipments on mortality applies to all other harms. Because Cutler has done no analysis to test his assumption, his opinions are unreliable and should be excluded.

Fourth, there is a critical mismatch between Rosenthal’s flawed analysis, which considers the relationship between detailing and opioid prescriptions, and Cutler’s flawed analysis, which looks at the relationship between opioid-related mortality and opioid shipments (which often differ from shipments) to arrive at his estimate of the impact of the alleged misconduct. This mismatch results in Cutler mixing apples (estimated effects of detailing on prescriptions) and oranges (estimated effects of shipments on mortality). And the mismatch matters. Replacing Cutler’s shipment data with Rosenthal’s prescription data reduces Cutler’s “average impact” percentage by 50 percent. (See Ex. 6, Kyle Report at ¶ 179). That Cutler’s model produces such drastically different results when changing the independent variable from shipments to prescriptions (*i.e.*, the very data Rosenthal used) shows that his model is unreliable. Indeed, “where, as here, very minor changes in arbitrarily selected model parameters can entirely alter the model’s conclusions, that model is insufficiently robust to withstand the scrutiny of Rule 702.” *Reed*, 49 F. Supp. 3d at 407.

3. *Cutler’s Estimate of Harms Attributable to All Opioids Is Based on*

Unreliable Data and Implicit Assumptions.

The final inputs in Cutler's model are his estimates of the magnitude of economic harms—like crimes, addiction treatments, and juvenile removals—that would not have occurred but for the existence of both prescription opioid medicines *and illegal opioids* like heroin and illicit fentanyl. These estimates, like the others, are speculative and unreliable because the data Cutler relies on do not support his estimates and he fails to account for the myriad factors that influence these inputs.

For example, the starting point for Cutler's estimate of crimes that would not have occurred but for the existence of opioids is a single data point from a 2002 national survey of inmates. Based only on the answers to a survey question about “crimes undertaken to obtain drugs or to obtain money to purchase drugs,” Cutler “estimates” an exact percentage of crimes (*e.g.*, 51.1% of cases of prostitution) that would not have occurred in Cuyahoga and Summit but for the existence of drugs for the twelve-year period from 2006 to 2017. (Ex. 1, Cutler Report at ¶ 38, Table III.3.) Cutler assumes that 100 percent of crimes that inmates self-reported were committed in order to get money to buy drugs were in fact *solely* caused by drugs, as opposed to the myriad other factors that might cause someone to commit a crime, such as poverty, mental disease, or individualized socio-economic circumstances. Moreover, Cutler does not use available crime data for Cuyahoga and Summit. Instead, he uses a national statistic from 2002 to identify an exact percentage of crimes in Cuyahoga and Summit from 2006-2017 that would not have occurred but for the existence of drugs: he simply “assume[s] that these percentages have not changed.” (*Id.*, n. 21.)

As another example, Cutler's estimate of juvenile removals attributable to opioids is unreliable because it is based on a single 2015 study measuring the percentage of children taken into custody in 2015 in Cuyahoga and Summit Counties who had parents who were using prescription or illicit opioids at the time of removal. (Ex. 1, Cutler Report at ¶ 44.) The first problem with this figure is that it does not suggest that the drug use caused the child removal, let

alone that it was the sole cause as Cutler assumes. Cutler fails to account for confounding factors that contribute to rates of child removal. Just as problematic, Cutler uses this single 2015 data point to extrapolate estimates for 2006 through 2017 under the assumption that opioid-related child removals track the trend in the annual changes of OUD treatment expenses in the counties. (*Id.*) This extrapolation assumes, without any support, that this single data point is representative of the share of foster care service harms for a twelve-year time period. That assumption is speculative and further renders Cutler's estimates of harms unreliable and inadmissible.

At bottom, all of Cutler's estimates ignore the facts and circumstances of the Track One Counties, and ignore the multi-faceted nature of the crimes, addictions, child removals, and other harms he analyzes. As a result, his models do not allow the trier of fact to identify which of these harms may be attributable to the conduct of any Defendant. On their own, these estimates are speculative and unreliable. When the product of these errors is combined and then multiplied by Cutler's other estimates, each of which suffers from their own fatal flaws, the end result falls far short of the standard for admissible expert testimony under Rule 702.

III. CONCLUSION

For the foregoing reasons, the Court should exclude Cutler's opinions and proposed testimony.

Dated: June 28, 2019

/s/ Carole S. Rendon

Carole S. Rendon
BAKER & HOSTETLER LLP
Key Tower 127 Public Square, Suite 2000
Cleveland, OH 44114-1214
Telephone: (216) 621- 0200
Fax: (216) 696-0740
crendon@bakerlaw.com

Respectfully Submitted,

/s/ Mark S. Cheffo

Mark S. Cheffo
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036
Tel: (212) 698-3500
Mark.Cheffo@dechert.com

Counsel for Defendants Endo Health Solutions Inc. and Endo Pharmaceuticals Inc.; Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc.

Co-Liaison Counsel for the Manufacturer Defendants

/s/ Kaspar Stoffelmayr
Kaspar Stoffelmayr
BARTLIT BECK LLP
54 West Hubbard Street
Chicago, IL 60654
Telephone: (312) 494-4434
Fax: (312) 494-4440
kaspar.stoffelmayr@bartlitbeck.com

Counsel for the Walgreens Defendants

Liaison Counsel for the Chain Pharmacy Defendants

/s/ Shannon E. McClure
Shannon E. McClure
REED SMITH LLP
Three Logan Square
1717 Arch Street, Suite 3100
Philadelphia, PA 19103
Telephone: (215) 851-8100
Fax: (215) 851-1420
smcclure@reedsmith.com

Counsel for Distributor Defendant AmerisourceBergen Drug Corporation

Co-Liaison Counsel for the Distributor Defendants

Counsel for Defendants Purdue Pharma L.P., Purdue Pharma Inc., and The Purdue Frederick Company

Co-Liaison Counsel for the Manufacturer Defendants

/s/ Enu Mainigi
WILLIAMS & CONNOLLY LLP
Enu Mainigi
725 Twelfth Street, N.W.
Washington, DC 20005
Telephone: (202) 434-5000
Fax: (202) 434-5029
emainigi@wc.com

Counsel for Defendant Cardinal Health, Inc.

Co-Liaison Counsel for the Distributor Defendants

/s/ Geoffrey Hobart
Geoffrey Hobart
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956
Telephone: (202) 662-5281
ghobart@cov.com

Counsel for Distributor Defendant McKesson Corporation

Co-Liaison Counsel for the Distributor Defendants

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **MANUFACTURER DEFENDANTS’
MOTION TO EXCLUDE DAVID CUTLER’S OPINIONS AND PROPOSED
TESTIMONY** and accompanying exhibits were served via email pursuant to the Court’s order.

By: /s/ Donna M. Welch
Donna M. Welch, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862-2000
donna.welch@kirkland.com